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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,381	03/06/2002	Huda Y. Zoghbi	HO-P01899US3(09906355)	1277
26271 7590 10/21/2003 FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			EXAMINER WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/980,381

### Applicant(s)

ZOGHBI ET AL.

### Examiner

Michael C. Wilson

### Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a mammal having a heterologous nucleic acid sequence replacing an allele of an atonal-associated nucleic acid sequence, wherein said heterologous sequence inactivates said allele.

Group II, claim(s) 1-17, drawn to a *Drosophila* having a heterologous nucleic acid sequence replacing an allele of an atonal-associated nucleic acid sequence, wherein said heterologous sequence inactivates said allele.

Group III, claim(s) 1-17, drawn to a zebrafish having a heterologous nucleic acid sequence replacing an allele of an atonal-associated nucleic acid sequence, wherein said heterologous sequence inactivates said allele.

Group IV, claim(s) 1-17, drawn to a frog having a heterologous nucleic acid sequence replacing an allele of an atonal-associated nucleic acid sequence, wherein said heterologous sequence inactivates said allele.

Group V, claim(s) 18-39, drawn to a method of treating an animal using an atonal-associated protein.

Group VI, claim(s) 18-39, drawn to a method of treating an animal using an atonal-associated nucleic acid sequence.

Group VII, claim(s) 40-46, drawn to compositions for therapy comprising atonal associated proteins.

Group VIII, claim(s) 40-46, drawn to compositions for therapy comprising atonal associated nucleic acid sequences.

Group IX, claim(s) 47 and 55, drawn to compositions for therapy comprising fusion proteins comprising atonal associated proteins.

Group X, claim(s) 48 and 55, drawn to compositions for therapy comprising nucleic acid sequences encoding fusion proteins comprising atonal associated proteins.

Group XI, claim(s) 49-54, drawn to method of treatment using fusion proteins comprising atonal associated proteins.

Group XII, claim(s) 49-54, drawn to method of treatment using nucleic acid sequences encoding fusion proteins comprising atonal associated proteins.

The inventions listed as Groups I-IV lack a common structure or function.

Section (f)(i)(A) and (f)(i)(B)(1) require the alternatives of a Markush Group have a common activity and structure. In this case, the structure of mammals, *Drosophila*, zebrafish and frogs are recognized in the art as different. In addition, the structure of an atonal-associated gene in each group would be different.

The inventions of Groups I-IV do not share the same special technical feature with Groups V-XII. The animals of I-IV have a genetically engineered disruption in an atonal-associated gene while the methods and products of Groups V-XII do not. Groups V-XII require using an amino acid or nucleic acid sequence of an atonal-associated gene while Groups I-IV require replacing an atonal-associated allele with a heterologous nucleic acid sequence.

The inventions of Groups V and VI do not share the same special technical feature because the method of Group V requires atonal-associated protein while the method of Group VI requires atonal-associated nucleic acid sequences.

The special technical feature of Groups V, VII, IX and XI, an atonal-associated protein, does not contribute over the prior art because such proteins were known (see pg 2, line 5, of specification which teaches the Math1 protein).

The special technical feature of Groups VI, VIII, X and XII, a nucleic acid sequence encoding an atonal-associated protein, does not contribute over the prior art because such nucleic acid sequences were known (see pg 2, line 5, of specification which teaches the Math1 protein).

The inventions of Groups VII and VIII do not share the same special technical feature because the method of Group VII requires atonal-associated protein while the method of Group VIII requires atonal-associated nucleic acid sequences. The structure and function of proteins and nucleic acids are distinct and separate.

The inventions of Groups IX and X do not share the same special technical feature because the product of Group IX requires an atonal-associated fusion protein while the product of Group X requires nucleic acid sequences encoding atonal-associated fusion proteins. The structure and function of proteins and nucleic acids are distinct and separate.

The inventions of Groups XI and XII do not share the same special technical feature because the method of Group XI requires atonal-associated protein while the method of Group XII requires atonal-associated nucleic acid sequences. The structure and function of proteins and nucleic acids are distinct and separate.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1) Math1, and
- 2) Hath1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-30, 33 and 36-55 are generic.

Claim 31 is specific to Math1.

Claims 32, 34 and 35 are specific to Hath1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Math1 and Hath1 have different structures and functions.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.


Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

  
**MICHAEL WILSON**  
**PRIMARY EXAMINER**